

## REMARKS

By way of this Response, Applicant re-asserts and incorporates by reference its prior arguments before the Office, including those arguments made in the responses submitted on April 29, 2004; December 15, 2006; July 30, 2007; February 21, 2008; and July 29, 2008.

### **I. Summary of the Office Action Mailed September 19, 2008**

In the Office Action mailed September 19, 2008, the Office restated its previous objection to the drawings. The Office rejected Claims 1 and 6-7 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Office also maintained its rejection of Claims 1-10 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,716,638 (Touitou) in view of U.S. Patent No. 6,509,005 (Peart) and “*Airways Response to Aerosolized Delta-9-Tetrahydrocannabinol: Preliminary Report*” by Vachon *et al.* (Vachon). Finally, the Office rejected Claims 9-10 under 35 U.S.C. § 103(a) as being unpatentable over Touitou in view of Peart and Vachon, and further in view of U.S. Patent No. 5,258,336 (LaMastro).

### **II. Status of the Claims**

Claims 1-10 were pending. By way of this response, Claims 1-10 have been amended. No new matter is presented by these amendments. Support for the amendments can be found at least at paragraphs 50-60 of the published application.

### **III. Objection to the Drawings**

The Office maintains its objection to the drawings. The Office states in support of its objection that the replacement drawings submitted on April 29, 2004 and December 15, 2006 do not correspond to the description of the drawings in the specification.

Applicant responds by respectfully directing the Office to Preliminary Amendment A, filed April 29, 2004, which Applicant believes the Office fails to consider in making its objection. Preliminary Amendment A included an amendment to the portion of the specification titled “Brief Description of the Drawings.” Specifically, Applicant amended the descriptions of the drawings in the specification to correspond with the replacement drawings submitted with Preliminary Amendment A. The amended specification accurately describes the replacement drawings, to which the Office presently objects. In making Preliminary Amendment A, Applicant noted that the amended drawings and descriptions did not contain new matter. Rather, the amended drawings were submitted to enhance legibility and simply divided the original data

from Figures 1-3, 11-12, 20-21 and 23-24 into multiple new figures. Given the lack of new matter presented therein, Applicant respectfully requests the Office enter the amendments to the specification set forth in Preliminary Amendment A and withdraw its objection to the drawings.

#### **IV. Response to the Rejections**

A. The Rejection Under 35 U.S.C. § 112 (Written Description) Should be Withdrawn

The Office rejected Claims 1 and 6-7 under 35 U.S.C. § 112 for failing to comply with the written description requirement. Specifically, the Office found that the specification failed to teach the presence of either a glycol without a lower concentration limit or an alcohol without an upper concentration limit. Without conceding the propriety of the rejection, Applicant has amended Claim 1 to include a range of concentrations for alcohol and glycol. Based on the following amendment, Applicant respectfully requests that the Office withdraw its rejection under 35 U.S.C. § 112.

B. The Rejections Under 35 U.S.C. § 103(a) Should be Withdrawn

1. *Claims 1-10 are not obvious over Touitou in view of Peart and Vachon.*

The Office rejected Claim 1-10 as obvious over Touitou in view of Peart and Vachon. Applicant respectfully submits that in view of its amendments, the presently pending claims are in condition for allowance.

The burden of establishing a *prima facie* case of obviousness lies with the Office. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be an apparent reason why a person of ordinary skill would have combined the prior art elements in the manner claimed. Second, there must be a reasonable expectation of success. Third, the references, when combined, must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the cited references and not in applicant's disclosure. *See* M.P.E.P. § 2143.

However, in order for references to be combined to form the basis of an obviousness rejection, it is "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way that the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). Although after *KSR* the teaching, suggestion and motivation requirement is no longer *sine qua non* of obviousness, a claim is "not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art.” *Id.* at 1741. Moreover, the Court’s holding in *KSR* did not “mention or effect the requirement that each and every claim limitation be found present in the combination of the prior art references before any analysis proceeds.” *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 846, 852 (N.D. Ill. 2007), *aff’d Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008).

Touitou, either alone or in combination with Peart and Vachon fails to teach or suggest all the elements of the pending claims. Touitou discloses a cosmetic or medical composition containing an active for topical administration. (Touitou at abstract.) The topical delivery system disclosed therein contains phospholipids, short chain alcohols and water that may also comprise a glycol and incorporates the active by forming an ethosomal emulsion. (Touitou 1:8-11.) Touitou utilizes a phospholipid in order to create the emulsion. (*Id.* 1:41-43.) Although Touitou provides generalized teachings regarding solubilized tetrahydrocannabinol, it relies entirely on the formation of a phospholipid emulsion.

Touitou teachings fail to teach or suggest all of the limitations of the claims as amended. In rejecting Applicant’s prior arguments over Touitou, the Office noted that Claim 1 did not exclude the presence of a phospholipid. In response, Applicant has amended Claim 1 to include a composition substantially free of a phospholipid. In reading Touitou, one skilled in the art would consider the presence of a phospholipid essential to the solubility of the active and maintenance of a suitable composition. Thus, the skilled artisan, in reading Touitou would not find it obvious to prepare an aerosolizable tetrahydrocannabinol composition without a phospholipid.

The teachings of Peart fail to remedy the deficiencies of Touitou. Peart discloses an aerosol propellant system for tetrahydrocannabinol that does not require the presence of a solvent. (Peart at 5:50-55.) Peart further discloses that if a solvent, such as ethanol is used, it should comprise less than 20%, and most preferably, less than 15% of the system. (Peart at 5:52-55.) Moreover, Peart teaches that the use of ethanol concentrations in excess of about 20% will result in a particle size too large to effectively administer tetrahydrocannabinol to the lungs. (Peart at 5:28-32.) Thus, Peart teaches a composition that relies upon low concentrations of alcohol, and specifically teaches away from the use of alcohol concentrations in excess of 20% of the solvent system. In contrast, the pending claims now state that alcohol should comprise between about 20% and about 70% of the solvent system.

Similarly, the disclosures in Vachon provide no improvement on the shortcomings of Touitou in regard to the present invention. Vachon discloses a solvent system for aerosol delivery of tetrahydrocannabinol comprising a ratio of propylene glycol to water of 9:1. (Vachon at 112.) These teachings stand in contrast to the claims of the present invention which have been amended to comprise a solvent system in which a glycol is present in the range of between about 20% and about 65% of the solvent system.

Based on the foregoing, Applicant respectfully submits that independent Claim 1 is not obvious over Touitou in view of Peart and Vachon. Claims 2-5 and 7-10 depend from independent Claim 1. Therefore, the patentability of independent Claim 1, as amended, over the prior art establishes the patentability of Claims 2-5 and 7-10. Therefore, Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) based on Touitou in view of Peart and Vachon be withdrawn.

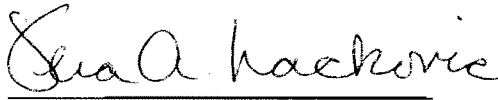
2. *The Claims 9-10 are not obvious over Touitou in view of Peart, Vachon and LaMastro.*

The Office rejected Claims 9 and 10 as obvious over Touitou in view of Peart, Vachon and LaMastro. Based on the remarks above, Touitou in view of Peart and Vachon fails to teach or suggest all the elements of Claim 1 as amended. The teachings of LaMastro do not remedy these deficiencies, as the teachings of LaMastro are directed toward the stability of compounds in amber bottles. Claims 9 and 10 depend from independent Claim 1. Therefore, the patentability of independent Claim 1, as amended, over the prior art establishes the patentability of Claims 9-10. Therefore, Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) based on Touitou in view of Peart, Vachon and LaMastro be withdrawn.

#### **IV. Conclusion**

Applicant believes that all of the pending claims are now in condition for allowance and respectfully requests notice to that effect. Should the Examiner wish to discuss the case, the Examiner is invited to call the undersigned at 312-701-8115.

Respectfully submitted,

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